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10/798,579	03/12/2004	Kazuko Shinozaki	081356-0210	6471

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EXAMINER	
KUMAR, VINOD	

ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,579	SHINOZAKI ET AL.	
	Examiner	Art Unit	
	Vinod Kumar	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6-9 and 11-15* is/are pending in the application.

4a) Of the above claim(s) *11-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6-9,14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of objections and rejections

1. Office acknowledges the receipt of Applicant's response filed on August 30, 2007. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 1, 4, 6-9, and newly added claims 11-15 are pending. Claims 1, 4, 6-9 and newly added claims 14-15 in conjunction with elected species rd29A promoter, and DREB1A coding sequence corresponding to SEQ ID NOs: 1 and 2 are examined on merits in this Office action. Objections to the specification are withdrawn in light of amendment to the specification filed in the paper of August 30, 2007. New Oath/Declaration filed in the paper of August 30, 2007 is accepted. All previous claim objections and rejections not set forth below have been withdrawn in view of claim amendments filed in the paper of August 30, 2007. This action is made FINAL.

Election/restriction

2. Applicant's claim amendment filed in the paper of August 30, 2007 contains claims that are directed to inventions that are independent or distinct from the invention originally claimed.

Since applicant has received an action on the merits for the originally presented invention (Group I), this invention has been constructively elected by original presentation for prosecution on the merits. Newly added claims 14-15 fall within the scope of originally presented invention would also be examined on merits along with

claims 1, 4, 6-9. Newly added SEQ ID NOs: 1 and 2 correspond to originally elected DREB1A DNA and its encoded protein would also be examined on merits along with originally presented invention.

Accordingly, newly added claims 11-13 of Group II and SEQ ID NOs: 3-28 are withdrawn from consideration as being directed to a non-elected inventions. See 37 CFR 1.142(b) and MPEP § 821.03.

A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

3. Applicants are advised that should claims 6 is found allowable, claims 7 and 8 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Claims 7 and 8 fail to limit claim 6. The transformed plant of claims 7 or 8 have same structural limitations as the transformed plant of parent claim 6. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object

to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

4. Claims 4 and 9 are objected for containing non-elected SEQ ID NOs.

5. Claims 1, 7, and 8 are also objected for containing non-elected subject matter.

Claim Rejections - 35 USC § 112

6. Claims 4 and 9 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic plant with improved rooting efficiency and/or prolonged vase life and a method of producing said transgenic plant comprising transformation of a plant with a DNA sequence encoding the DREB1A protein of SEQ ID NO: 2, does not reasonably provide enablement for (a) a DNA sequence which has less than 100% sequence identity to the nucleotide sequence of DREB1A (SEQ ID NO: 1) encoding DREB1A protein (SEQ ID NO: 2). The claim(s) contain subject matter which was not described in the specification in such a way as to enable one skilled in the art which it pertains, or which it is most nearly connected, to make and/or use the invention for the reasons of record stated in the Office action mailed on March 27, 2007. Applicants traverse the rejection in the paper filed on August 30, 2007.

Applicants argue that the specification discloses the common sequences among the DREB proteins, and thus a skilled artisan is enabled to select the mutants that are 94% homologous to the disclosed DREB sequences while retaining the function of

binding to the stress-responsive element based description in the specification. (response, page 16, lines 11-16).

Applicant's arguments were fully considered but were not found to be persuasive. Claims 4 and 9 are directed to a nucleotide sequence having 94% sequence identity to SEQ ID NO: 1, which would encompass encoded proteins having unspecified amino acid changes compared to SEQ ID NO: 2. A 94% sequence identity to instant SEQ ID NO: 1 of 933 nucleotides in length, and comprising 648 nucleotides of coding sequence would encode proteins having less than 80% sequence identity to instant SEQ ID NO: 2.

It is maintained that while the specification provides guidance on using a nucleotide sequence encoding SEQ ID NO: 2, in a method of producing transgenic plants with improved rooting efficiency and/or prolonged vase life. However, specification does not provide guidance on using sequences encoding proteins having less than 100% sequence identity to SEQ ID NO: 2, in a method of producing said transgenic plants.

It is further maintained that making amino acid changes in SEQ ID NO: 2 protein is unpredictable. While it is known that many amino acid substitutions, additions or deletions are generally possible in any given protein the positions within the protein's sequence where such amino acid changes can be made with a reasonable expectation of success (without altering protein function) are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various

sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These regions can tolerate only relatively conservative substitutions or no substitutions. See Keskin et al., Thornton et al. and Guo et al. as discussed in previous Office action. It is further maintained that neither the state of art nor Applicants provide guidance as to how inoperable embodiments can be readily eliminated other than random trial and error. The additions, deletions or substitutions in one or more amino acid residues would also encompass changes in the functionally important domain(s) of the encoded protein. In the absence of guidance, it would have been highly unpredictable at the time the claimed invention was made that a DNA sequence having at least 94% sequence identity to SEQ ID NO: 1, could have been used in a method of producing a transgenic plant with improved rooting efficiency and/or prolonged vase life.

In the absence of adequate guidance, it is maintained that undue experimentation would have been required by a skilled artisan at the time claimed invention was made to determine how to use a DNA sequence having at least 94% sequence identity to SEQ ID NO: 1, in a method of producing a transgenic plant exhibiting improved rooting efficiency and/or prolonged vase life. See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, as discussed previously and further outlined above, it is maintained that undue experimentation would have been required by one skilled in the art at the time the claimed invention was made to practice the invention commensurate in scope with these claims. Accordingly, the rejection is maintained.

7. Claims 4 and 9 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record stated in the Office action mailed on March 27, 2007. Applicant's response filed in the paper of August 30, 2007 did not address issues related to rejection under written description. Accordingly, the rejection is maintained.

Claim Rejections - 35 USC § 102

8. Claims 1, 4, 6-9 remain, and newly added claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Kasuga et al. (Nature Biotechnology, vol. 17, pp. 287-291, March 1999) for the reasons of record stated in the Office action mailed on March 27, 2007. Applicants traverse the rejection in the paper filed on August 30, 2007.

Applicants argue that the claimed plant comprises certain proteins, e.g., proteins having the ability of inhibiting ethylene-forming enzyme, a protein associated with cytokinin, and a protein associated with cytokinin. Applicants further argue that the

factors relating to vase life, propagation ability using scions and rooting efficacy are, a protein having the ability of inhibiting ethylene-forming enzyme, a protein relating to cytokinin, and a protein relating to auxin. Applicants further argue that with the aid of these proteins, the claimed plant is able to have improved rooting efficacy, prolonged vase life and propagation ability using scions. Applicants further argue that Kasuga et al. disclose an *Arabidopsis* plant which does not appear to be associated with rooting efficacy, prolonged vase life, and propagation ability via scions (response, page 17, lines 11-21).

Applicant's arguments were fully considered but were not found to be persuasive. It is maintained that Kasuga et al. disclose a transgenic plant and a method of making said transgenic plant comprising transformation of said plant with an expression vector comprising stress-inducible rd29A promoter operably linked to drive expression of a nucleotide sequence (100% sequence identity to instant DREB1A DNA or SEQ ID NO: 1) encoding stress-inducible and the DNA binding protein of DREB1A (SEQ ID NO: 2), wherein said DREB1A protein binds to a stress-responsive element of a stress-inducible promoter in response to environmental stresses like, freezing, drought or salt. The reference further discloses a recombinant vector, stress (drought, salt or freezing) tolerant transgenic plant and a method of producing said transgenic plant comprising said stress-inducible promoter operably linked with a stress inducible coding region of *Arabidopsis* CBF3 (a DREB transcription factor). The transgenic plants exhibited increased tolerance to salt and drought (dehydration) stresses. See in particular, page 287, abstract; page 288, Figures 1 and 2; page 289, Figures 3-5; page 290, Table 1; 1st

and 2nd columns of page 290; page 291, experimental protocol. It may be emphasized that DREB1A DNA used in Kasuga et al. has 100% sequence identity to instant SEQ ID NO: 1 which encodes a protein having 100% sequence identity to instant SEQ ID NO: 2. This is also cited in Kasuga et al. (see in particular, page 287, 2nd paragraph, right column).

It is also maintained that the property of regulating the transcription of a gene comprising a stress-responsive element is inherent to the method using DREB1A DNA encoding DREB1A protein (100% identity to instant SEQ ID NO: 2) disclosed in the reference.

It is further maintained that the property of improved rooting efficiency and/or prolonged vase life is inherent to the method of producing a transformed plant comprising DREB1A operably linked to rd29A promoter disclosed in the reference.

If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, rather than any distinct definition of any of the claimed invention's limitations, then preamble is not considered a limitation and is of no significance to claim construction. See also MPEP § 716.07.

Applicants are also reminded that when the reference relied on expressly anticipates all of the elements of the claimed invention, the reference is presumed to be operable or enabling. See *In re Sasse*, 629. F.2d 675, 207 USPQ 107 (CCPA 1980). See also MPEP § 716.07.

It is important to note that something which is old does not become patentable upon the discovery of a new property. The discovery of a previously unappreciated

property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. See *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. See also *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., factors relating to vase life, propagation ability using scions and rooting efficacy are, a protein having the ability of inhibiting ethylene-forming enzyme, a protein relating to cytokinin, and a protein relating to auxin) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Also see *In re Cruciferous Sprout Litig.*, 301 F.3d 1343,1346-48, 64 USPQ2d 1202, 1204-05 (Fed. Cir. 2002) where a claim at issue was directed to a method of preparing a food rich in glucosinolates wherein cruciferous sprouts are harvested prior to the 2-leaf stage. The court held that the preamble phrase "rich in glucosinolates" helps define the claimed invention, as evidenced by the specification and prosecution history, and thus is a limitation of the claim (although the claim was anticipated by prior

art that produced sprouts inherently "rich in glucosinolates"). Furthermore, see *Integra LifeSciences I Ltd. V. Merck KGaA* 50 USPQ2d 1846, 1850 (DC Scalif 1999), which teaches that where the prior art teaches all of the required steps to practice the claimed method and no additional manipulation is required to produce the claimed result, then prior art anticipates the claimed invention.

Accordingly, Kasuga et al. anticipated the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Newly added claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasuga et al. (Nature Biotechnology, vol. 17, pp. 287-291, March 1999; Applicant's IDS) in view of Applicants' admitted stated of the prior art, Dalton et al. (Plant Science, 132:31-43, 1998).

Kasuga et al. teach a transgenic plant and a method of making said transgenic plant comprising transformation of said plant with an expression vector comprising stress-inducible rd29A promoter operably linked to drive expression of a nucleotide sequence (100% sequence identity to instant DREB1A DNA or SEQ ID NO: 1) encoding stress-inducible and the DNA binding protein of DREB1A (SEQ ID NO: 2),

wherein said DREB1A binds to a stress-responsive element of a stress-inducible promoter in response to environmental stresses like, freezing, drought or salt. The reference further teaches a recombinant vector, stress (drought, salt or freezing) tolerant transgenic plant and a method of producing said transgenic plant comprising said stress-inducible promoter operably linked with a stress inducible coding region of *Arabidopsis* CBF3 (a DREB transcription factor). See in particular, page 287, abstract; page 288, Figures 1 and 2; page 289, Figures 3-5; page 290, Table 1; 1st and 2nd columns of page 290; page 291, experimental protocol.

Kasuga et al. do not teach silicon carbide whisker-mediated plant transformation.

Applicants' admitted state of the prior art teaches use of silicon-carbide whisker in plant transformation. See in particular, page 32, right column. This citation addresses the limitation of newly added claim 15.

It would have been obvious to use any method of plant transformation that were well known in the prior art as admitted by the Applicants (see page 38, 3rd paragraph) including using the cited Dalton et al. silicon-carbide whisker based plant transformation method to arrive at the claimed invention with reasonable expectation of success.

Accordingly, the claimed invention as a whole is prima facie obvious over the combined teachings of the prior art.

Conclusions

10. Claims 1, 4, 6-9 remain, and newly added claims14-15 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is set to expire within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER